REMARKS

Status of the Claims

The present Office Action addresses and rejects claims 7-28 and 41-44.

Applicant thanks the Examiner for the telephone interview on June 11, 2008 with Applicant's representatives Bill Geary and Christina Sperry. Allowance of the claims was not agreed upon in the interview, and Applicant respectfully requests reconsideration in view of the amendments and remarks herein.

Amendments to the Claims

Claim 7 is amended to recite that the first and second pledgets and the first securing element are bioimplantable and that the suture, the first and second pledgets, and the first securing element are effective to fix adjacent layers of living tissue. Claim 8 is amended to recite that the second securing element is bioimplantable. Claim 41 is amended to recite that the first and second pledgets and the first and second securing element are bioimplantable and that the suture, the first and second pledgets, and the first and second securing element are effective to fix adjacent layers of living tissue. Support for these amendments can be found throughout the specification and drawings, such as in paragraphs [0004], [0032], [0037], and [0039] of the published application.

Claim 11 is amended to recite a deployment instrument having first and second tubes configured to deliver the first and second securing elements in the first position through the tubes and through the respective hole formed in said tissue. Support for this amendment can be found throughout the specification and drawings, such as in figure 10 and in paragraphs [0010] and [0046]-[0049] of the published application.

Claim 44 is amended to correct typographical errors.

No new matter is added.

Rejections Pursuant to 35 U.S.C. § 102

Claims 11-13 and 15 are rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,592,609 ("Bonutti"). Applicant respectfully disagrees.

Independent claim 11 recites a tissue fixation device including a suture suitable for in vivo placement in a human or animal body, a first biocompatible securing element connected to a first portion of the suture, and a second biocompatible securing element connected to a second portion of the suture. Each of the first and second securing elements are rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element to pass through a respective hole formed in human or animal tissue to a second position when the tissue fixation device is deployed that inhibits each securing element from passing through the respective hole formed in the human or animal tissue. The tissue fixation device also includes a deployment instrument having first and second tubes configured to deliver the first and second securing elements in the first position through the tubes and through the respective hole formed in said tissue.

Bonutti Does Not Disclose A Deployment Instrument Having First And Second Tubes

Bonutti does not teach or suggest a deployment instrument having first and second tubes configured to deliver the first and second securing elements in the first position through the tubes and through the respective hole formed in said tissue. The only element that could be a deployment instrument disclosed in Bonutti has a single tube 58, as shown in Figure 3, reproduced at right.

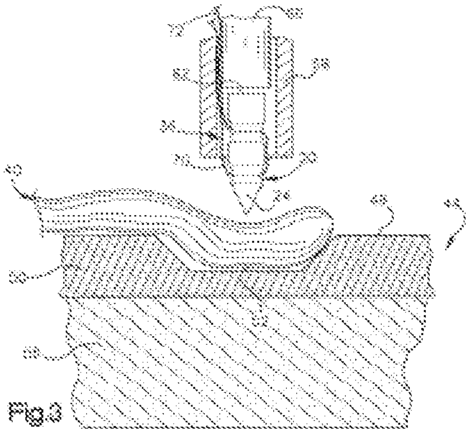


Fig.3

Bonutti Does Not Disclose The Claimed Securing Elements

Bonutti does not teach or suggest that each of the first and second securing elements are *rotatable* from a first position during deployment of the tissue fixation device that is suitable for each securing element to *pass through a respective hole* formed in human or animal tissue to a second position when the tissue fixation device is deployed that *inhibits each securing element from passing through the respective hole* formed in the human or animal tissue.

First, there is no teaching or suggestion in Bonutti that its force distribution member 196 and anchor 188, which the Examiner likens to securing elements, are suitable to pass through respective holes in human or animal tissue. Indeed, they are not suitable because for the device of Bonutti to properly function, both the force distribution member 196 and the anchor 188 would have to pass through the *same* hole in tissue, not through respective holes. It is clear from Figure 9, reproduced below, that the force distribution member 196 does not and cannot pass through a hole formed in soft tissue layers 180, 182 that the anchor 188 passes through to reach the underside of the bottom soft tissue layer 182 because the force distribution member 196 is adjacent to the upper major side surface of the top tissue layer 180. (*See* Col. 14, lines 21-34; Col. 16, lines 7-16.) There are no other holes in tissue described in Bonutti, but the force distribution member 196 could arguably be passed through a hole in tissue to reach the upper major side surface of the top tissue layer 180. However, at least for surgical convenience and safety because the force distribution member 196 is connected to the same suture 190 as the anchor 188, that hole would be the same one used to advance the anchor 188 to the upper major side surface of the top tissue layer 180 before the anchor 188 penetrates and passes through the top tissue layer 180. Therefore, the anchor 188 and the force distribution member 196 do not pass through a *respective hole* and are not suitable to do so.

Second, whatever hole in tissue the force distribution member 196 passes through, Bonutti is silent on position of the force distribution member 196 during deployment, only describing the force distribution member 196 as deployed as shown in Figure 9. Thus, there is no teaching or suggestion that the force distribution member 196 is rotatable from a first position during deployment and to a second position when the device deployed to inhibit it from passing through the hole it passed through to reach the upper major side surface of the top tissue layer 180.

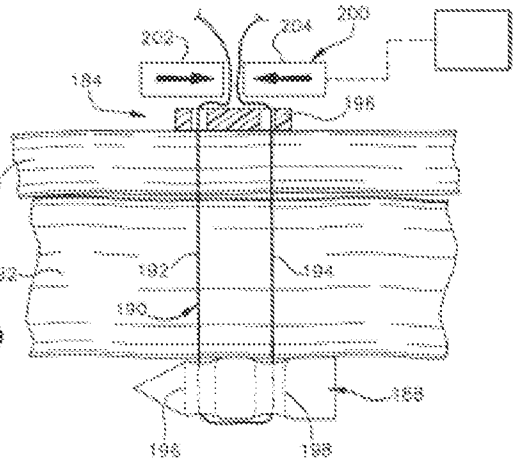


Fig9

Third, even if the force distribution member 196 is somehow considered to be rotatable from a first position during deployment to a second position when the tissue fixation device is deployed, there is no teaching or suggestion in Bonutti that the force distribution member 196 is inhibited or is even suitable to be inhibited from passing through whatever hole in tissue it passed through during deployment. The deployed *position* of the force distribution member 196 illustrated in Figure 9 does not *inhibit* the force distribution member 196 from *passing through* whatever hole in tissue it passed through to reach that position. If the force distribution member 196 had to reach that position by passing through a hole in tissue, there is no indication in Bonutti that the force distribution member's deployed position inhibits it from again passing through the hole. At best, while the force distribution member 196 is deployed and pressed against the top tissue layer 180, the connector assembly 200, not the force distribution member's position, can prevent the force distribution member 196 from moving "backwards" and passing through the hole.

Accordingly, independent claim 11, as well as claims 12, 13, and 15 which depend therefrom, distinguish over Bonutti and represent allowable subject matter.

Rejections Pursuant to 35 U.S.C. § 103

Merser, Robbins, Whaley, La Torraca, and Deschenes Are Non-Analogous Art

In various § 103 rejections discussed further below, the Examiner individually or in various combinations asserts U.S. Patent No. 3,399,432 ("Merser"), U.S. Patent No. 2,104,885 ("Robbins"), UK Patent Application No. 2075829 ("Whaley"), U.S. Patent No. 3,900,925 ("La Torraca"), and U.S. Patent No. 5,671,507 ("Deschenes"). None of these references, alone or in any combination, can be relied on to formulate an obviousness rejection over the pending claims because Merser, Robbins, Whaley, La Torraca, and Deschenes are non-analogous art.

In order to rely on a reference in analyzing the obviousness of the subject matter at issue, the reference must be analogous prior art. A reference is "analogous" if (1) the reference is within the field of the inventor's endeavor, and if it is not then (2) the reference must be reasonably pertinent to the particular problem with which the inventor was involved. (See MPEP § 2141(a).) Merser, Robbins, Whaley, La Torraca, and Deschenes are not within the field of the inventor's endeavor, and none are reasonably pertinent to the problem to be solved.

Each of Merser, Robbins, Whaley, La Torraca, and Deschenes are directed toward buttons used in clothing and other fabric-sewing contexts. The present invention, on the other hand, is directed toward surgical methods and devices. No person having ordinary skill in the art would rely on a reference directed toward buttons. These are completely distinct, not reasonably related fields of endeavor concerned with very different problems. Accordingly, buttons are not within the field of the inventors' endeavor, namely surgical methods and devices, nor reasonably pertinent to the particular problem with which the inventors were involved, namely reconfiguring tissue. Accordingly, Merser, Robbins, Whaley, La Torraca, and Deschenes each represent non-analogous art that cannot be relied on individually or in any combination to reject the claimed invention.

Merser, Robbins, and Deschenes Do Not Disclose Bioimplantable Elements or Elements Effective To Fix Adjacent Layers of Living Tissue

Independent claims 7 and 41 recite that the first and second pledgets and the first securing element are bioimplantable. Claim 41 also recites that the second securing element is bioimplantable. The Examiner cites Merser, Robbins, and Deschenes in various § 103 rejections of claims 7 and 41 discussed further below, but none of these cited references disclose any bioimplantable elements, much less first and second bioimplantable pledgets and first and second bioimplantable securing elements.

Merser, Robbins, and Deschenes are directed toward buttons used in clothing and other fabric-sewing contexts. Such buttons are not disclosed to be implantable within a body nor to be effective to fix tissue. Indeed, they would almost certainly lead to infection, other injury, or death if implanted in a body and/or used to fix tissue.

Furthermore, the buttons disclosed in Merser, Robbins, and Deschenes would not be made from a material allowing them to be bioimplantable because there is simply no disclosed context in which clothing and other fabric would be implanted in a body so as to require bioimplantability. Such buttons may contact an outside surface of skin and hence be made from a material safe for skin contact, but all everyday objects, e.g., staplers, paper clips, newspapers, tires, etc., are typically made to be safe for external body contact. It is unreasonable to presume that buttons and other such everyday objects are or need to be made for implantation in a body simply because they may contact the outside surface of a body.

Accordingly, for at least these reasons, claims 7 and 41, as well as their various dependent claims, distinguish over Merser, Robbins, and Deschenes, either taken alone or in any combination, and represent allowable subject matter.

Merser, Robbins, and Deschenes Do Not Disclose A Pledget

Independent claims 7 and 41 each recite first and second pledgets. In various § 103 rejections of claims 7 and 41 discussed further below, the Examiner argues that Merser, Robbins, and Deschenes each disclose a pledget. The Examiner asserts that the term "pledget" should be interpreted to include the members or buttons disclosed in Merser, Robbins, and Deschenes because "the members or buttons are 'small, flat compress[es]…used to protect,' where the members or buttons are usable to compress and protect portions of fabrics or garments." (*See* Office Action, page 9.) Applicant respectfully disagrees.

At the outset, Applicant notes that the term "pledget" is not functional language but instead is a structural term having structural meaning. Buttons and pledgets are different physical objects. A "button" is simply not a "pledget" under any reasonable interpretation. For example, a table having four legs would not reasonably be unpatentable over a reference disclosing a dog having four legs just because a table and a dog both have legs because a "table" and a "dog" are different physical objects and words with different meanings.

Furthermore, the Examiner has not provided adequate reason or support for his interpretation of the term "pledget" in independent claims 7 and 41. The Examiner's interpretation is inconsistent with the Applicant's specification and with the ordinary and customary meaning of the term as it is used in this context. The meaning of the term "pledget" as used in claims 7 and 41 should not be construed in a "lexicographic vacuum, but in the context of the specification and drawings." (Toro Co. v. White Consolidated Industries Inc., 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999); *see* MPEP § 2111.01.) The term "pledget" is clearly a specific medical term. Paragraphs

[0036] through [0039] of the published application indicate that a tissue fixation device can include first and second pledgets spaced apart by tissue. These paragraphs clearly characterize the meaning of the term "pledget" as it is used throughout the application, a medical device for closing or protecting a wound or tissue. Such a characterization is completely inconsistent with the Examiner's interpretation of the term because buttons are not pledgets but are non-medical fasteners used in clothing and other fabric-sewing contexts that are inappropriate, if not harmful, to use for medical purposes in a human or animal body. Further, the Applicant's drawings provide support to the specification's characterization of the term "pledget" by showing devices used in a surgical context.

The Taber's Cyclopedic Medical Dictionary definition previously submitted by the Applicant in the Response to the Office Action dated April 24, 2007 is clearly a *medical* dictionary in a *medical* context and is fully consistent with the Applicant's characterization of the term in the specification and drawings. The Examiner, however, has completely overlooked the medical context of the definition in applying it to non-medical buttons and has provided no reason or basis for interpreting the term "pledget" in a manner inconsistent with the present application. It appears that the only reason for choosing such an interpretation is to formulate a rejection of the claims. While the Examiner can give the claims their broadest possible interpretation, the "broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." In re Cortright, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999); see MPEP § 2111. A person skilled in the art would understand that the tissue fixation device must include a "pledget" as used in the Applicant's claims and specification, not buttons used for sewing as suggested by the Examiner.

For all of these reasons, Applicant respectfully asks that the Examiner reconsider his interpretation of the term "pledget" and allow independent claims 7 and 41, as well as their various dependent claims.

Merser In View Of Robbins

Claims 7-10, 42, and 43 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Merser in view of Robbins. Applicant respectfully disagrees.

Independent claim 7 recites a tissue fixation device including a suture, a first bioimplantable pledget having at least one through hole formed therein with a first portion of the suture passing through the at least one through hole in the first pledget and a second portion of the suture configured to inhibit the second portion from passing through the at least one through hole in the first pledget, a second bioimplantable pledget having at least one through hole formed therein with the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed, and a first bioimplantable securing element connected to a portion of the suture. The first securing element is rotatable from a first orientation in which the securing element is oriented at least substantially parallel to the at least one through hole formed in the first pledget and the second pledget, to a second orientation in which the securing element is oriented at least substantially perpendicular to the at least one through hole in the second pledget. The suture, the first and second pledgets, and the first securing element are effective to fix adjacent layers of living tissue

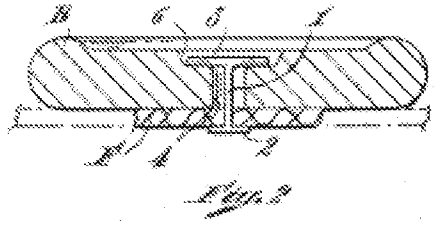
As discussed above, Merser and Robbins are non-analogous art and each fail to teach or even suggest a pledget as the term is properly interpreted in view of the specification, drawings, and the ordinary and customary meaning of the term as it is used in this context. Instead, Merser and Robbins both disclose sewing buttons that are clearly not medical devices, much less bioimplantable, and are not described in any sort of medical context.

There is No Motivation to Combine Merser and Robbins

Moreover, there is no motivation to combine Merser and Robbins. The Examiner relies on Merser to teach the claimed invention but admits that Merser fails to disclose a second pledget having at least one through hole. The Examiner thus relies on Robbins for this feature, arguing that "[i]t would have been obvious to one having ordinary skill in the art, in view of Robbins, to include a second pledget with the fixation device of Merser. Such a pledget or backing would protect fabric or tissue from chafing or ripping by first and second securing elements placed in contact with the second pledget, and it would prevent the securing elements from being pulled through the holes in the relatively more pliant fabric or tissue." (*See* Office Action, pages 3-4.) Applicant respectfully disagrees.

Even if Robbins does demonstrate a need for a second button as asserted by the Examiner (*see* Office Action, page 9), a person skilled in the art at the time the invention was made would not have had reason to combine the second button of Robbins with the first button of Merser. As discussed below, the predictable result of using the second button of Robbins with the first button of Merser would serve no purpose if not yield a non-functioning device, so a person skilled in the art would not have combined Merser and Robbins. Accordingly, there is no reason or motivation to combine the references to teach or suggest claim 7.

The strongest rationale for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. (See MPEP § 2144). The combination of Merser with Robbins does not render claim 7 obvious because a person skilled in the art would not reasonably expect a second button to serve any purpose with the device of Merser. As shown, for example, in Figure 2 of Merser, reproduced at right, the head (2) of Merser's device is large enough to not chafe, rip, or be pulled through the fabric (F). Including the second button would make Merser's device more complicated and more time consuming to apply, which is contrary to Merser's concern with simplicity and speed of fastening. Furthermore, there is no indication that Merser's method of fastening would remain functional if the second button of Robbins was combined with Merser's device. Thus, at least for these reasons, a person having ordinary skill in the art would have no reason or motivation to combine the second button of Robbins with Merser because it would serve no purpose if not render Merser's method non-functioning.



Accordingly, for at least these reasons, independent claim 7, as well as claims 8-19, 42, and 43 which depend therefrom, distinguish over Merser and Robbins, taken alone or together, and represent allowable subject matter.

Whaley

Claims 11-14, 16, 17, and 27-28 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Whaley. Applicant respectfully disagrees.

Whaley Does Not Disclose A Deployment Instrument

Whaley does not teach or suggest a deployment instrument having first and second tubes configured to deliver the first and second securing elements in the first position through the tubes and through the respective hole formed in said tissue. Indeed, there is not any sort of deployment instrument disclosed in Whaley at all.

Whaley Does Not Disclose the Claimed Securing Elements

Whaley does not teach or suggest that each of the first and second securing elements are rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element to *pass through a respective hole* formed in human or animal tissue to a second position when the tissue fixation device is deployed that *inhibits each securing element from passing through the respective hole* formed in the human or animal tissue. Similar to that discussed above regarding Bonutti, there is no teaching or suggestion in Whaley that its retaining bar 2 and head 3, which the Examiner likens to securing elements, pass through respective holes in human or animal tissue. The retaining bar 2 and the head 3 would apparently have to pass through the same hole for the device to be functional. There is also no indication that the *position* of either the retaining bar 2 or the head 3 are inhibited from passing through whatever hole in tissue they respectively pass through in tissue during deployment.

It Would Not Have Been Obvious To Use A Suture Suitable For In Vivo Placement Or Biocompatible Securing Elements With Whaley

Moreover, the Examiner relies on Whaley to teach the claimed invention but admits that Whaley fails to disclose a suture suitable for in vivo placement in a human or animal body or that the first and second securing elements are biocompatible. The Examiner argues that "[i]t would have been obvious to one having ordinary skill in the art to form the suture and elements out of biocompatible materials, since the fixation device is exposed to or in contact with human and/or animal bodies (e.g., when the device is being used with upholstery for human and animal furniture." (*See* Office Action, page 5.) The Examiner further argues that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to apply biocompatible materials in the fixation device, since it has been held within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended user as a matter of obvious design choice." (*See id.*) Applicant respectfully disagrees.

As discussed above, a person having ordinary skill in the art to which the subject matter sought to be patented applies would not look to the non-analogous art of Whaley at all. However, even if such a person did turn to Whaley, the fixation device of Whaley is not applied *in vivo*. Whaley is directed to upholstery ties. Upholstery made from animal skin is not sewn or applied with fasteners while the animal skin is still alive or even when the animal skin is still attached to the rest of a living animal. Furthermore, if Whaley's upholstery ties are being used in furniture used by humans or animals, no portion of the tie is suitable for *in vivo placement in* a human or animal body. Furniture is obviously not placed inside human or animal bodies, and as discussed above, it is simply not reasonable to choose materials for the ties of Whaley in anticipation of such an event. It is therefore not obvious for any element, much less a suture or a securing element, disclosed in Whaley to be made suitable for in vivo placement or to be made from biocompatible materials safe for use in a living human or animal body.

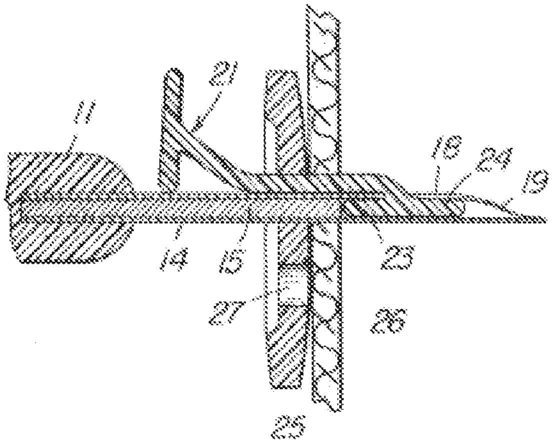
Accordingly, for at least these reasons, independent claim 11, as well as claims 12-14, 16, 17, and 27-28 which depend therefrom, distinguish over Whaley and represent allowable subject matter.

La Torraca

Claims 11, 18, 20-24, and 26 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over La Torraca. Applicant respectfully disagrees.

La Torraca Does Not Disclose A Deployment Instrument Having First And Second Tubes

La Torraca does not teach or suggest a deployment instrument having first and second tubes configured to deliver the first and second securing elements in the first position through the tubes and through the respective hole formed in said tissue. The only element that could be a deployment instrument disclosed in La Torraca is a single hollow needle 14, as shown in Figure 3, reproduced below.



La Torraca Does Not Disclose the Claimed Securing Elements

La Torraca does not teach or suggest that each of the first and second securing elements are rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element to *pass through a respective hole* formed in human or animal tissue to a second position when the tissue fixation device is deployed that *inhibits each securing element from passing through the respective hole* formed in the human or animal tissue. Similar to that discussed above regarding Bonutti and Whaley, there is no teaching or suggestion in La Torraca that its legs 24, which the Examiner likens to securing elements, pass through respective holes in human or animal tissue. The legs 24 would apparently have to pass through the same hole for the device to be functional because they are part of a singular fastener 21 loaded onto the needle 14 for deployment. There is also no indication that the *position* of either of the legs 24 inhibits the legs 24 from passing through whatever hole in tissue they respectively pass through during deployment.

It Would Not Have Been Obvious To Use A Suture Suitable For In Vivo Placement Or Biocompatible Securing Elements With La Torraca

Moreover, the Examiner relies on La Torraca to teach the claimed invention but admits that La Torraca fails to disclose a suture suitable for in vivo placement in a human or animal body or that the first and second securing elements are biocompatible. The Examiner argues that "[i]t would have been obvious to one having ordinary skill in the art to form the suture and elements out of biocompatible materials, since the fixation device is exposed to or in contact with human and/or animal bodies (e.g., when the device is being used with clothing fabrics for humans and animals."

(*See* Office Action, page 6.) The Examiner further argues that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to apply biocompatible materials in the fixation device, since it has been held within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended user as a matter of obvious design choice." (*See id.*) Applicant respectfully disagrees.

As discussed above, a person having ordinary skill in the art to which the subject matter sought to be patented applies would not look to the non-analogous art of La Torraca at all. However, even if such a person did turn to La Torraca, the fixation device of La Torraca is not applied *in vivo*. La Torraca is directed to a button attacher for clothing or other fabric-composed items. No portion of La Torraca's device is suitable for *in vivo placement in* a human or animal body. Clothing and other fabrics obviously do not enter human or animal bodies, and it is simply not reasonable to choose materials for the device of La Torraca in anticipation of such an event. It is therefore not obvious for any element, much less a suture or a securing element, disclosed in La Torraca to be made suitable for in vivo placement or to be made from biocompatible materials safe for use in a living human or animal body.

Accordingly, for at least these reasons, independent claim 11, as well as claims 18, 20-24, and 26 which depend therefrom, distinguish over La Torraca and represent allowable subject matter.

Deschenes

Claims 11 and 25 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Deschenes. Applicant respectfully disagrees.

Deschenes Does Not Disclose A Deployment Instrument

Deschenes does not teach or suggest a deployment instrument having first and second tubes configured to deliver the first and second securing elements in the first position through the tubes and through the respective hole formed in said tissue. Indeed, there is not any sort of deployment instrument disclosed in Deschenes at all.

Deschenes Does Not Disclose the Claimed Securing Elements

Deschenes does not teach or suggest that each of the first and second securing elements are rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element to *pass through a respective hole* formed in human or animal tissue to a second position when the tissue fixation device is deployed that *inhibits each securing element from passing through the respective hole* formed in the human or animal tissue. Similar to that discussed above regarding Bonutti, Whaley, and La Torraca, there is no teaching or suggestion in Deschenes that its feet 21, 23, which the Examiner likens to securing elements, pass through respective holes in human or animal tissue. The feet 21, 23 would apparently have to pass through the same hole for the device to be functional. There is also no indication that the *position* of either of the feet 21, 23 inhibits the feet 21, 23 from passing through whatever hole in tissue they respectively pass through during deployment.

It Would Not Have Been Obvious To Use A Suture Suitable For In Vivo Placement Or Biocompatible Securing Elements With Deschenes

Moreover, the Examiner relies on Deschenes to teach the claimed invention but admits that Deschenes fails to disclose a suture suitable for in vivo placement in a human or animal body or that the first and second securing elements are biocompatible. The Examiner argues that "[i]t would have been obvious to one having ordinary skill in the art to form the suture and elements out of biocompatible materials, since the fixation device is exposed to or in contact with human and/or animal bodies (e.g., when the device is being used with fabrics or garments for humans and animals." (*See* Office Action, pages 6-7.) The Examiner further argues that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to apply biocompatible materials in the fixation device, since it has been held within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended user as a matter of obvious design choice." (*See* Office Action, page 7) Applicant respectfully disagrees.

As discussed above, a person having ordinary skill in the art to which the subject matter sought to be patented applies would not look to the non-analogous art of Deschenes at all. However, even if such a person did turn to Deschenes, the fixation device of Deschenes is not applied *in vivo*. Deschenes is directed to a fastener for garments or other fabric-composed items.

No portion of Deschenes's device is suitable for *in vivo placement in* a human or animal body. Garments and other fabrics obviously do not enter human or animal bodies, and it is simply not reasonable to choose materials for the device of Deschenes in anticipation of such an event. It is therefore not obvious for any element, much less a suture or a securing element, disclosed in Deschenes to be made suitable for in vivo placement or to be made from biocompatible materials safe for use in a living human or animal body.

Accordingly, for at least these reasons, independent claim 11, as well as claim 25 which depends therefrom, distinguish over Deschenes and represent allowable subject matter.

La Torraca in view of Robbins

Claim 19 is rejected pursuant to 35 U.S.C. § 103(a) as being obvious over La Torraca in view of Robbins. Applicant respectfully disagrees.

At least for the reasons explained above, La Torraca does not make obvious independent claim 11, from which claim 19 depends. Robbins is only relied on for a dependent claim feature and does not remedy the deficiencies of La Torraca. Furthermore, as also explained above, Robbins does not teach or suggest a pledget. Accordingly, claim 19 is allowable at least because it depends from an allowable base claim.

Deschenes in view of Robbins

Claims 41 and 44 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Deschenes in view of Robbins. Applicant respectfully disagrees.

Independent claim 41 recites a tissue fixation device including a suture, a first bioimplantable pledget having a plurality of through holes formed therein with the suture passing through the through holes in the first pledget, a second bioimplantable pledget having a plurality of through holes formed therein with the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed, a first bioimplantable securing element having a sharp tip and a proximal end configured for removable attachment to an instrument, and a second bioimplantable securing element having a sharp tip and a proximal end configured for removable attachment to an instrument. The first and second securing elements are coupled to the suture. The suture, the first and second pledgets, and the first and second securing elements are effective to fix adjacent layers of living tissue.

As discussed above, Deschenes and Robbins are non-analogous art and each fail to teach or even suggest a pledget as the term is properly interpreted in view of the specification, drawings, and the ordinary and customary meaning of the term as it is used in this context. Instead, Deschenes and Robbins both disclose sewing buttons that are clearly not medical devices, much less bioimplantable, and are not described in any sort of medical context.

Accordingly, for at least these reasons, independent claim 41, as well as claim 44 which depends therefrom, distinguish over Deschenes and Robbins, taken alone or together, and represent allowable subject matter.

Conclusion

Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

Dated: June 16, 2008

Respectfully submitted,

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